PHILIP MORRIS PRODUCTS INC.

International Operations Services
QUALITY ASSURANCE
Richmond, VA

TO: Ms. Becky Tobey DATE: October 17, 1997

FROM: Luisa Sánchez White

SUBJECT: **AUDIT REPORT FOR PRODUCT TESTING LABORATORY, OCTOBER 07, 1997.**

On October 07, 1997, I conducted an audit to ISO Guide 25 for the Product Testing Laboratory (PTL), Philip Morris Research and Development, accompanied by Ms. Beckey Tobey, the ISO Coordinator.

When preparing for the audit I reviewed the Product Testing Laboratory's Quality Manual as well as the Standard Operating Procedures. The questions asked during the audit were prepared based on these two references, as well as, the ISO Guide 25, 1997. The focus of my audit was in the laboratory's compliance to the written documentation.
The audit started with a review of the Quality Management System with the ISO Coordinator. At my request, evidence was provided of the internal audits performed at PTL and the system that closes the Corrective action loop, when findings are observed.

The system outlined in the Quality Manual, for which PTL's policies and practices are reviewed with all personnel, on a yearly basis, and the current system for the testing of PTL's technicians' adherence to specified testing procedures were also reviewed with the Quality Coordinator, and found in compliance.

I also verified PTL's system for Management reviews and actions that were taken to close the loop on external audit findings from two previous years. I reviewed the process for which departmental Policy and Procedure Instructions, PPI's, are updated. All findings were in compliance.

PTL Receiving: I met with the section Supervisor and reviewed two employees' training records and the system for identifying the employees' training needs; I followed up on an SOP for the receiving, logging and conditioning of a sample for ISO testing with a laboratory technician. Observations were in compliance to the Quality Manual and respective SOP.

Physical Testing lab: Escorted by the Quality Coordinator and the lab Supervisor, I selected a Circumference FLM 200 instrument and requested from the technician operating it to walk me through the procedure of Measuring Circumference. The same technician was asked to show me the calibration logbook, process for gage calibration, etc. The audit process was repeated for the PPM 100 Porosity instrument. All findings were in compliance.
System for traceability of raw data, as well as Certificates of calibration of the Instruments were made available at my request. Uncertainties of the testing methods were also verified and were found to be in compliance with the SOP's . Instrument calibration processes and verification frequency for instrumentation selected were also found in compliance with SOP's . The lab Supervisor was requested the training records for two technicians, they were made available and found up to date.

Smoking laboratory: A sample of the Domestic brands was chosen for the audit. I requested to be walked through the process of ensuring the Quality Control of the Smoking data. A Data Handling Associate Analyst showed the process through which she receives Smoking and GC data in the computer and goes through the verification process. This was found in conformance to SOP's.
I then looked at the Smoking process to observe the system for Control of Nonconforming testing and/or calibration work. One of the manual Smoking machines was chosen. The current practice is based on Control Charts calibrated after a machine Capability Study for each machine. This system was found in compliance with its designed objectives.
Capability and Control Charting for Process Control was evidence presented for compliance with preventive actions. In fact, previous practices were that a single monitor specification and associated tolerances were used for the Smoking machine process control; however, it did not regard the individual machine Capability. As data is collected, an extensive Statistical study will be completed on port to port variation in the Smoking machines. The objective is to ensure the continuous improvement of the Smoking process.

Logs of the Smoking machine parameters and calibration and of the TPM Robotic balance calibration were observed and found in compliance. Environmental Conditions monitoring for ISO and FTC Smoking were verified in two of the cubicles.
Demonstration of traceability of Smoking machine data and TPM weights was requested for specific brands smoked on one manual Smoking machine. A bar code system traced the data to the Smoking lab and to the Receiving area.

Smoking Laboratory, continued.
The balance verification weights were reviewed and found to be in calibration order, the certificate indicating traceability to NIST.
A copy of TPM records for a run performed 3 weeks before was requested and readily retrievable.

Data Analysis: I asked for a copy of a Domestic C.I. test report from the previous semester and requested demonstration of traceability for one brand analyzed December 1996. I wanted to see how the monitor cigarette that was used to validate the Smoking process for that brand had performed in December 1996. At the time, the lab Analyst thought her database would not allow her to go that far, therefore; brought me to one of the Statistics technician to retrieve it. While the Statistics technician was trying to retrieve the monitor data for me, the lab Analyst came back with a document from her database containing the data I requested. Therefore, traceability was demonstrated in the two computer systems.

The PTL Data analysis system for the flagging of suspect data was illustrated by a Computer Analyst and found in compliance with SOP's. The process for detection and rejection of outliers was followed and considered in agreement with SOP's.
I requested to see the QC verification of the "Run the CI expert System" software but the system was not in operation at the time.
I asked a Data Analyst to explain the "Customer Concern" system at PTL. I then chose a previous customer concern from the PTL logbook, and asked about the actions taken to resolve the concern and to correct the problem from its root cause. Evidence was shown as to the new approaches and steps in the process to prevent recurrence of the problem (Steering team).
A copy of the employees' training records and system for identification of further training needs was requested and found in compliance.

Engineering support: Copies of certificates of calibration of PTL environmental monitoring systems were requested, provided and found in order. The training records for maintenance technicians at Smoking machines were requested and found in order. Logs of the maintenance records of the upgraded Filtrona machines and of the preventive maintenance for a Robotic balance were found in order and compliance with the SOP's. At request of the logs for Smoking machine airflow, I was taken to the cubicles themselves where they are kept and were found in order. Copy of a certificate of calibration requested, of the Puff Volume meter was shown, and found traceable to DIN German Standards.

Analytical Lab: I interviewed one GC technician and verified the GC's maintenance and maintenance records, calibration logbook and construction and purpose of calibration curve. All found in compliance with the SOP.
I asked another lab technician to walk me through the process of preparing Nic-Water standards, validating those standards versus previous ones, and the traceability of the balance where the Nic-Water standards were weighed. Procedures were found in compliance with SOP's.
All glassware used in preparation of those Standards found in compliance to the SOP. The uncertainty for the testing method is expressed based on the Confidence Interval for a pre-specified number of ports. All found in compliance to the written SOP's.
Traceability and compliance to records retention policies of Water/Nic Chromatograms were observed, and evidenced in compliance to PTL Quality Manual. Training records for one randomly chosen lab technician were found in order. The process for Menthol determination in Smoke was followed with one lab technician and found in agreement with SOP's. Bar coding used for traceability of the samples found in compliance; Pyrex graduated cylinders for the solvent volume check found in compliance with written SOP. The testing methodology for Menthol in TPM was found in compliance with written SOP; however, the reagent grade **Menthol is certified by the supplier as 99% and this is not taken into consideration when calculating the concentration of the working standards for the GC. The 1% error not currently in consideration, may or may not make a difference in the final Menthol content reported. Verification is recommended.**

The Gas Phase Analytical Laboratory performs the CO testing in the cigarettes' Gas phase. A laboratory technician walked me through the CO Smoking machine process, including the sample receiving, sample selection, and machine calibration and testing. The process was found in compliance with written SOP's. An observation was made to the lab Supervisor, however; as to the fact that **uncertainty for the CO testing method is not currently stated in the SOP**.

Physical Testing lab, B-Shift: The process for the Oven Volatiles, (O.V.) determination was illustrated by a technician from the B-Shift and found in compliance. While at the O.V. lab, I reviewed the O.V. logbook; balance calibration logbook, verification weights status; oven control charts and temperature monitoring. All found in compliance with SOP's.

Verification of computer system database calculations: According to PTL's Quality Manual, a manual verification performed by recording and processing of data for at least two samples for all applicable Physical tests is performed every year. Evidence was shown as to the compliance with the written statements in PTL's Quality Manual. Computer and manual data and calculations were shown and explained, for samples from Physical testing, Smoking lab's (initial and final TPM weights), and Analytical lab (blanks vs. External calibration in the case of GC's).

Observation:
Although the certificates of calibration for the various PTL laboratories showed calibrations that are traceable either Nationally (i.e. NIST) and/or Internationally (i.e. German DIN); some of the verification standards and or instruments/devices are certified by laboratories that are not ISO Guide 25 accredited.

An example is the balance weights and the RTD capillaries used by PTL. They are traceable to NIST and/or equivalent institution; however, the Standards and calibration laboratory that performed those calibrations (an in-house laboratory) is not currently accredited to ISO Guide 25. The Quality Coordinator, as well as all Supervisors at PTL are aware of the fact that this is viewed by third party auditors as a non-compliance of the testing lab. A third party audit will require the testing laboratory to request a "waiver" for these findings. Currently, the in-house Standards and Calibration laboratory is preparing for accreditation to ISO Guide 25 and ISO Guide 58.

The certificates of calibration from contractor Johnsons Controls for the wall devices for continuous monitoring of temperature-Relative Humidity are also traceable to Internationally recognized standards. But Johnsons Controls is not ISO Guide 25 accredited.
The response from the Quality Coordinator and Maintenance Supervisor to this is that by 1998, General Eastern will be the supplier of these calibration services instead.

General Comments:

The personnel at PTL was very professional and supportive during conduction of the audit. The general attitude of personnel at PTL was that of being open and cooperative for information and/or explanations requested. The Quality Management system shows evidence of maturity and strength. I observed a high level of awareness towards the Quality Management System and the know how to keep it strong. No major deficiencies were found during the audit. Observations and suggestions for improvements were discussed with Joe Garman, A-Shift section Leader, and Becky Tobey, Quality Coordinator. A briefing on findings was discussed with Dr. Ken Podraza, Manager, PTL Laboratory.

Yours Sincerely,

Luisa S. White

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cc. J. Garman

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